

## NIH POLICY ON SHARING OF MODEL ORGANISMS FOR BIOMEDICAL RESEARCH

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National Institutes of Health (NIH)

As a public sponsor of biomedical research, NIH is committed to supporting national and international efforts that encourage the sharing and dissemination of important research resources. NIH is also cognizant of the need to support reasonable incentive structures that facilitate commercial development or translation of basic research findings. Restricted availability of unique research resources, upon which further studies are dependent, can impede the advancement of research. Conversely, sharing biomaterials, reagents and data in a timely manner has been an essential element in the rapid progress that has been made in research on many model organisms for biomedical research. The NIH is interested in continuing to ensure that the research resources developed with NIH funding are made readily available in a timely fashion to the research community for further research, development, and application, in the expectation that this will further the research enterprise and accelerate the development of products and knowledge of benefit to the public. At the same time, NIH recognizes the rights of grantees and contractors to elect and retain title to subject inventions developed with federal funding pursuant to the Bayh-Dole Act.

This notice reaffirms NIH support for the concept of timely sharing and distribution of biomedical research resources [See NIH Grants Policy Statement ([http://grants.nih.gov/grants/policy/nihgps\\_2003/index.htm](http://grants.nih.gov/grants/policy/nihgps_2003/index.htm)); NIH Research Tools Policy, also referred to as Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources: Final Notice ([http://ott.od.nih.gov/NewPages/RTguide\\_final.html](http://ott.od.nih.gov/NewPages/RTguide_final.html)), December 1999], and provides further guidance with particular attention on model organisms for biomedical research. Model organisms include but are not restricted to mammalian models, such as the mouse and rat; and non-mammalian models, such as budding yeast, social amoebae, round worm, fruit fly, zebra fish, and frog. [See NIH Model Organism for Biomedical Research Website at <http://www.nih.gov/science/models/> for information about NIH activities related to these resources]. Research resources to be shared include genetically modified or mutant organisms, sperm, embryos, protocols for genetic and phenotypic screens, mutagenesis protocols, and genetic and phenotypic data for all mutant strains. Genetically modified organisms are those in which mutations have been induced by chemicals, irradiation, transposons or transgenesis (e.g., knockouts and injection of DNA into blastocysts) or those in which spontaneous mutations have occurred. By sharing of research resources and, thus, avoiding the duplication of very expensive efforts to generate model organism models, the NIH is able to support more investigators than if these useful models had to be generated in duplicate by more than one NIH funded investigator.

This statement applies to extramural investigators funded by NIH grants, cooperative agreements, and contracts, including SBIR and STTR awards. Guidelines already in place for the intramural research program are consistent with those for the extramural community (for example, see <http://www1.od.nih.gov/oir/sourcebook/ethic-conduct/resources.htm>).

To further extant NIH resource sharing policies, all investigators submitting an NIH application or contract proposal beginning with the October 1, 2004 receipt date, are expected to include in the application/proposal a description of a specific plan for sharing and distributing unique model organism research resources generated using NIH funding so that other researchers can benefit from these resources, OR state appropriate reasons for why such sharing is restricted or not possible. Unlike the NIH Data Sharing Policy, the submission of a model organism sharing plan is NOT subject to a cost threshold of \$500,000 or more in direct costs in any one year, and is expected to be included in all applications where the development of model organisms is anticipated. (The NIH Final Statement on Data Sharing is available at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html>)

The adequacy of plans for sharing model organisms will be considered by reviewers when a competing application is evaluated. Reviewers will be asked to describe their assessment of the sharing plan in an administrative note and, normally, will not include their assessment in the overall priority score. For some special initiatives, such as Request for Applications (RFA) and Request for Proposals (RFP) specifically directed to the development of model organisms, reviewers may be asked to integrate their evaluation of the plan for sharing with other review criteria and factor their assessment into the overall evaluation of scientific merit.

As the expectations and tools available to facilitate model organism sharing continue to evolve, maximum flexibility is encouraged to allow for renegotiations during the project period at the request of either the Institute/Center (IC) or the funded institution in response to materially new and/or unforeseen information or developments. Applicants/Offerors responding to a RFA or RFP may find additional requirements related to resource or data sharing in the specific announcement. Applicants/Offerors are encouraged to discuss their sharing plans with their NIH program contact, who also can direct them to existing repositories or national coordinating centers. A reasonable time frame for periodic deposition of material and associated data should be specified in the application.

Applicants/Offerors are also expected to address as part of the sharing plan if, or how, they will exercise their intellectual property rights while making model organisms and research resources available to the broader scientific community. At a minimum, the plan should address the following questions in a clear and concise manner:

- o Will material transfers be made with no more restrictive terms than in a Simple Letter Agreement (SLA) ([http://ott.od.nih.gov/NewPages/Rtguide\\_final.html#sla](http://ott.od.nih.gov/NewPages/Rtguide_final.html#sla))

for the transfer of materials or the Uniform Biological Material Transfer Agreement (UBMTA)( <http://ott.od.nih.gov/NewPages/UBMTA.pdf>)?

o How would inappropriate “reach-through” requirements (as discussed in the NIH Research Tools Policy) on materials transferred be addressed?

o How will technologies remain widely available and accessible to the research community, for example, if any intellectual property rights arise for which a patent application may be filed?

Applicants/Offerors are encouraged to inform and/or confer with their institutional offices of technology transfer and other relevant institutional offices to develop plans for addressing these requirements. Applicants/Offerors are reminded that the research institution is required to submit a report of each subject invention to NIH within two months after the inventor discloses it in writing to institutional personnel responsible for invention matters.

In their evaluation of non-competing continuation applications, NIH program staff may consider, as part of the criteria for continued funding, adequate progress in model organism sharing as well as a demonstrated willingness to make research resources developed during the project widely available to the research community. Failure to comply with NIH research resource sharing policies, guidelines, and the accepted plan may also be carefully considered by NIH staff in future funding decisions for the investigator and the investigator’s institution.

Investigators may request funds in their application/proposal to defray reasonable costs associated with sharing materials or data or transfer of model organisms and associated data to appropriate repositories. Investigators are encouraged to confer with their technology transfer office and/or office of sponsored programs for guidance.

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